CHAPTER 2

PROCEDURES FOR COMMERCIAL LABORATORIES

Section I. Validation Procedures

2-1. Initiation Procedures. A laboratory validation will be initiated after a commercial laboratory successfully bids a contract to support USACE HTRW response activities. A written request from a USACE TM/COR to the Coordinator initiates the laboratory validation process. A request format as shown in Figure 2-1 or a memorandum with all information contained in Figure 2-1 may be submitted to the Coordinator by mail or facsimile, as follows:

U.S. Army Corps of Engineers
ATTN: CEMRD-ED-EC (Laboratory Validation Coordinator)
HTRW Mandatory Center of Expertise
Missouri River Division
12565 West Center Road
Omaha, Nebraska 68144-3869

Voice: (402) 221-7494
FAX : (402) 221-7403

2-2. Implementation Procedures.

a. Upon receiving the laboratory evaluation request, the Coordinator will immediately check the laboratory's current validation status. If the laboratory is currently validated by the USACE for all project-required analytical parameters and has no performance problems noted, the Coordinator will notify the USACE TM/COR in writing of the Committee's approval within ten working days. If the laboratory is not currently validated by the USACE for all project-required analytical parameters, the Coordinator will immediately notify the USACE TM/COR by phone and initiate the laboratory validation process.

b. The laboratory validation process may take up to 12 weeks; therefore, the primary contractor and/or the USACE TM/COR should plan the project schedule to allow adequate time for laboratory validation and the USACE TM/COR should submit a request for evaluation to the Coordinator as early as possible. The Committee shall also make a concerted effort to ensure that the validation process is completed within the time frame required by the project. Unless projects require specialized chemical analyses or a quick turnaround of large number of samples, normally a minimal number of commercial laboratories should be used for each contract and be requested for validation.

TO: CEMRD-ED-EC FROM:_____ DATE:____/_____/____

SUBJECT: REQUEST FOR EVALUATION OF COMMERCIAL LABORATORY

Project Name:_____
Location:_____ State:_____
Contract No:_____ Type: POL TANK REMOVAL:___HTRW:___
Program: SF:___ FUDS :___ IRP:___ AF(ACC):_____ OTHER:_____
Phase: PA/SI:____RI/SI:____ RD:____RA:____ RFA :___ RFI:____ CMS:___

Approximate Sampling Dates:_____
Project-Specific Sample Turnaround Time:_____

USACE Technical Manager:_____
Address:_____
Phone:_____ FAX:_____

A-E/Contractor:_____ State:_____
Lab Name:_____
Address:_____
POC:_____
Phone:_____ FAX:_____

Required analytical parameters, methods, and approximate number of samples to be taken for above project.

PARAMETERS & METHODS	No. of LIQUID SAMPLES	No. of SOLID SAMPLES

State or other laboratory certifications that will be required for this project:_____

Note: If the laboratory is planning to subcontract any samples to another laboratory or location, all of these laboratories shall be evaluated separately. This format should be sent for verification of laboratory status regardless of expiration date on the list of validated laboratories.

Figure 2-1 Laboratory Evaluation Request Format

c. Although three major sequential steps are involved in the laboratory validation process, the actual steps required for each laboratory, as determined by the Committee, may be different, based on the following guidelines:

(1) For commercial laboratories that have never been validated under the USACE HTRW Program: A full, three-step laboratory validation process conducted by the Committee representatives is required.

(2) For commercial laboratories that have expired laboratory validation under the USACE HTRW Program: When the next contract is awarded to support USACE HTRW response activities, a revalidation will be required. After considering the use of the laboratory and the laboratory's previous performance, the Committee will determine which of the three steps will apply to the revalidation process.

(3) For commercial laboratories that are currently validated under the USACE HTRW Program: When the laboratory obtains a new contract(s) to support USACE HTRW response activities during its validation period, the capability and past performance on USACE HTRW projects shall be verified by the Committee. If different analytes and/or matrices are involved in the new contract(s), the laboratory must pass additional PE samples for those different analytes and/or matrices. If past performance has been satisfactory, the USACE TM/COR will be notified that no further actions are required and the laboratory is validated for all parameters of the new contract(s); otherwise, a full laboratory validation might be required as determined by the Committee on a case-by-case basis.

(4) For commercial laboratories whose validations might expire while the laboratories are working on ongoing projects: A revalidation will be required if a USACE TM/COR expects that an ongoing project will extend more than six months beyond the validation expiration date. The Committee will determine which validation steps are required for the revalidation process on a case-by-case basis. If the completion of an ongoing project is anticipated within six months after the expiration date, no actions are required.

(5) For on-site mobile laboratories: The same procedures used for validation/revalidation of an off-site "fixed" commercial laboratory will apply to an on-site mobile laboratory. However, no PE samples will be sent to a mobile laboratory until the mobile laboratory is mobilized and settled down at the project site. Due to the timing of PE sample analysis and the quick turnaround nature of mobile laboratory, the laboratory

inspection for an on-site mobile laboratory can be coordinated with project schedule. The validation status of an on-site mobile laboratory terminates if the laboratory moves to a new location prior to the validation expiration date. After an on-site mobile laboratory is mobilized to a new location, another full laboratory validation is required. No laboratory validation is required for an on-site mobile laboratory that only performs field screening analysis, i.e., Level II data quality.

(6) For commercial laboratories to be used for underground storage tank removal projects:

(a) For projects involving removal of tanks, both underground storage tanks (USTs) and aboveground storage tanks (ASTs), that have been used only for storage of petroleum, oils, or lubricants (POL), there are two alternatives to the validation process. These two alternatives apply only to predesign sampling of UST organic phase contents and soil sampling during removal. They do not apply to investigations required by groundwater contamination or extensive soil contamination.

Alternative 1: State certified laboratories may be used without USACE validation, if the state considers its certification to be applicable to UST removal. When this alternative is selected, a document in the project file must identify the individual responsible for coordination with the state.

Alternative 2: The HTRW MCX will conduct an abbreviated laboratory validation process if a USACE TM/COR submits a request for evaluation of commercial laboratory. The laboratory must submit its qualification documents including laboratory quality management manual (LQMM) and standard operating procedures (SOP) for the required analyses to the Coordinator for review. If the laboratory has been recently validated for the project-specific analytical parameters and has no performance problems with USACE projects, the laboratory may be exempted from PE sample analysis. However, if performance problems with the commercial laboratories are noted, a full laboratory validation by the Committee representatives will be performed.

(b) If alternative 2 is selected, an on-site inspection by the Committee representatives for POL UST/AST removal projects is generally exempted. The USACE division laboratory that serves as the project QA laboratory, the geographic district, and/or FOA are encouraged to perform inspection per the protocols addressed in this manual. If inspections are not conducted by the Committee representatives, the inspectors must be trained and certified by the Committee prior to on-site inspections.

The Committee shall be kept fully informed of these inspections and will be free to send representative(s) to the inspections at any time. The same inspection approach and checklists as described in this manual shall also be used by the "non-Committee representative" inspectors.

(c) A commercial laboratory validated for POL UST/AST removal projects may not be used to support other HTRW projects unless a full laboratory validation is performed by the Committee representatives. A full laboratory validation will be required for a UST/AST site investigation if leaking tanks cause groundwater contamination or severe soil contamination. For projects involving removal of non-POL tanks that have contained HTRW substances or wastes, a full laboratory validation conducted by the Committee is required.

2-3. Implementation Procedure Steps. A full laboratory validation involves three major sequential steps conducted by the Committee representatives. Ordinarily, each step in the sequence is completed before the subsequent step is initiated.

a. Step 1: Review of Qualification Documents.

(1) The Coordinator will inform a commercial laboratory by phone or mail of the upcoming laboratory validation and request for review copies of the laboratory's qualification documents, including generic LQMM and other appropriate documents such as SOPs, laboratory certificates, etc. The laboratory shall submit the required documents within five working days of the request. If the laboratory does not have a LQMM, USACE will not pay for the preparation of this document. The submittals should provide appropriate information (including personnel, facilities, instrumentation, SOPs, QA/QC policies, etc.) for the Committee to evaluate and assess the laboratory's technical capabilities on the project-required chemical analyses.

(2) Upon receiving the qualification documents, one of the committee members will be designated to compare the laboratory's in-house technical capabilities with the project requirements. Within two working days, the designee will verbally convey the results of this comparison to the Coordinator. If the comparison identifies deficiencies, the Coordinator or designee shall: immediately contact the laboratory to verify the deficiencies; coordinate any follow-up actions; and verbally notify the USACE TM/COR of the problems. If deficiencies are verified, the Coordinator or designee shall present the findings to the Committee and recommend termination of the validation. Upon approval by the Committee, the Coordinator shall immediately issue a follow-up letter to notify the USACE TM/COR and the

commercial laboratory of the problems, the Committee's decision of termination of the validation process, and the need for selection of another laboratory. If it appears that the capabilities of the laboratory are adequate to meet the project requirements, the Coordinator shall immediately mail the following documents to the laboratory for information and action, and step 2 will be initiated.

- Information for Commercial Analytical Chemistry Laboratories Undergoing Validation by the U.S. Army Corps of Engineers (Appendix C),
- Guidelines for Analyzing and Reporting Performance Evaluation Samples from the U.S. Army Corps of Engineers (Appendix D), and
- Preliminary Questionnaire for the U.S. Army Corps of Engineers Validation Program for Analytical Laboratories (Appendix E).

(3) The laboratory shall complete and return a copy of the completed preliminary questionnaire within ten working days from the date of receipt.

b. Step 2: Analysis of PE Samples.

(1) The Coordinator will arrange to have PE samples sent to the laboratory for analysis. Project-specific PE samples are mandatory and must be passed. In addition to project-specific PE samples, the laboratory may volunteer for validation of additional parameters by requesting non-project-specific PE samples. The cost for the first set of project-specific PE samples will be covered by the USACE HTRW program management funds. However, for any additional sets or any non-project-specific PE samples, the laboratory will be responsible for the expense of PE samples which ranges from $100 to $300 per method, per matrix, and per shipment. Appendix F shows the fee schedule, which is subject to annual review and adjustment without notice to reflect currency value fluctuations or changes in program administration costs, for PE samples available from the USACE. A commercial laboratory is not reimbursed for costs involved in the analysis of the PE samples.

(2) If a nonstandard analytical method or a modified standard analytical method is required, the laboratory shall submit its in-house SOP and method validation data (including method detection limits, precision, accuracy, QC limits, chromatograms, etc.) to the Coordinator for review and approval. PE samples for a nonstandard or a modified standard method will

only be sent after the Committee has reviewed and approved the method. PE samples for validation of a mobile laboratory shall only be sent after the laboratory is mobilized to the project site and all instruments are calibrated. The Committee may request instrument calibration data for review prior to shipping PE samples to a mobile laboratory.

(3) Analysis of PE Samples.

(a) In general, the PE samples are method- and matrix-specific. A commercial laboratory may not subcontract PE samples to another laboratory. A commercial laboratory must use project-required analytical methods for analyses of all project-specific PE samples unless otherwise instructed by the Coordinator. The sources of analytical methods usually required for USACE HTRW projects, and therefore for the PE sample analysis, in a preferential order are as follows:

- Test Methods for Evaluating Solid Waste, SW-846 (Third Edition, Revision 0, September 1986; Revision 1, July 1992; or the most recently promulgated revisions.)

- Statements of Work for Organics Analysis, Inorganics Analysis, and Dioxin Analysis, (USEPA Contract Laboratory Program, Document Number OLM02.0, ILM03.0, DFLMO1.0, and the most recent revisions.)

- Methods for Chemical Analysis of Water and Wastes, EPA-600/4-79-020 (Revised March 1983 or the most recently promulgated revisions.)

- Methods for the Determination of Organic Compounds in Drinking Water, EPA-600/4-88/039 (December 1988 or the most recently promulgated revisions.)

- Other standard and published methods of the most recent versions from USEPA, American Society for Testing and Materials (ASTM), American Public Health Association, American Water Works Association, Water Pollution Control Federation, United States Geological Survey (USGS), National Institute for Occupational Safety and Health (NIOSH), Department of Energy (DOE), etc.

(b) The parameters and commonly required methods for PE sample analyses are listed in Appendix F. Any changes or modifications in analytical methods for PE samples must be preapproved by the Committee. Use of nonstandard or modified standard analytical methods without a proapproval from the Committee may result in failure of PE sample analysis.

(c) PE samples will be prepared and sent out from reliable suppliers by overnight express delivery. All PE samples shall be preserved and shipped according to USACE, USEPA, and DOT regulations and guidelines. Full chain-of-custody shall be maintained for each shipment of PE samples. The analytical laboratory of Waterways Experiment Station (WES) in Vicksburg, Mississippi, and the Missouri River Division Laboratory (MRDL) in Omaha, Nebraska, are currently two of the major USACE PE sample suppliers. Guidance for PE sample suppliers including WES, MRDL, and commercial vendors on PE sample preparation, handling, and validation are described in Appendix G. The general guidelines for PE sample analysis and reporting by a commercial laboratory are described in Appendix D. Special sample-specific instructions for PE sample analysis will be provided by PE sample suppliers on the chain-of-custody document enclosed in each PE sample shipment. Any questions on PE sample analyses should be directed to the Coordinator. A commercial laboratory shall also conduct all method-specific QC analyses which include but are not limited to method blank, replicate, matrix spike, matrix spike duplicate, and surrogate spike. If the amount of material constituting the PE samples is not enough for all QC analyses, the QC analyses shall be performed on spiked reagent water.

(4) Reports of PE Sample Results.

(a) A commercial laboratory shall report the concentrations of all target analytes listed in the required analytical methods, including estimated values and the quantitation limits for target analytes not detected. The quantitation limit of each analyte must meet or be less than those specified in the method for the particular matrix. Except for petroleum hydrocarbons PE samples, all soil/sediment PE sample analyses shall be reported on a dry-weight basis along with percent moisture. For petroleum hydrocarbons PE samples, the results shall be reported on an “as-received” basis (i.e., no correction should be made for moisture content). Neither should any data be corrected for spike recoveries nor for any contamination found in trip blank or laboratory’s method blank.

(b) All method-specific QC data associated with the PE sample analysis, including method blank, replicate analysis, spike recovery, etc., shall be reported. Written reports of all PE sample analyses are to be received by the PE sample suppliers within 20 working days after receipt of the samples. For projects requiring quick turnaround for field sample analyses, the turnaround times for the PE samples may be reduced. For example, due to the often short lead-time and the quick turnaround nature of most UST removal projects, the turnaround

time for PE sample analysis needed for UST removal projects will range from five to ten working days depending on the number of parameters required. Failure to analyze the PE samples correctly and within the required time frame may result in termination of the validation process. An additional copy of all PE sample reports shall be sent to the Coordinator for review. Upon request by the Coordinator, a commercial laboratory shall also submit for review all raw data including sample preparation and run logs, calibrations, chromatograms, calculations, etc. A commercial laboratory may use its standard data package to report PE sample results; however, the data package shall be sequentially numbered and contain, as a minimum, the following information:

- Table of contents.
- A case narrative including problems encountered with PE sample analysis.
- A chain-of-custody report.
- Sample preparation information.
- Analytical results for all target analytes plus method citations and quantitation limits.
- Summary of method-specific QC results for assessment of precision and accuracy.
- Phone conversation records on major issues related to PE sample analysis.

(c) Failure to submit the requested information within a required time frame will be considered as non-responsive and may result in termination of the validation procedure. It is the laboratory's responsibility to keep the Coordinator informed early of any problems with PE sample analyses that would affect the return of results within a required time frame.

(5) Evaluation of PE Sample Results.

(a) After receipt of PE sample data reports, the PE sample suppliers should immediately evaluate the analytical data quality based on statistically established confidence limits and generally accepted QC indicators for accuracy and precision. The PE sample results will be compared in the following manner:

- with the prepared concentrations of PE samples that are used as the absolute recovery comparators, and

- with the statistical mean and standard deviations reported by a group of referee and/or peer laboratories.

(b) The general acceptance limits for analyte quantitation will be established statistically at the 95 percent confidence based on referee laboratories and/or peer group results. The Committee shall review the evaluation reports and determine the pass/fail status for PE sample results. The general criteria for acceptance of PE sample results are as follows:

- All Chemical Analyses:

  All method-specific QC data are reported and within method-specified criteria.

- Multianalyte Organic Analyses:

  No more than one target compound outside three sigma confidence limits and no more than two target compounds between two and three sigma limits. False negatives and false positives are considered as outside three sigma.

- Metal Analysis:

  No metal elements outside three sigma confidence limits and no more than two metal elements between two and three sigma limits. False negatives and false positives are considered as outside three sigma.

- Classical Chemical Analyses:

  All data are within two sigma.

(c) Within ten working days after receipt of PE sample results, the PE sample suppliers shall send the Coordinator a written evaluation report. At a minimum, the report shall contain the: laboratory name; location (city and state); dates that PE samples were delivered; laboratory's PE sample results; dates results were received; true values and/or acceptable limits for each target analyte; narratives for special problems or issues; follow-ups on failed parameter; and recommendations for pass/fail. If requested by the Coordinator, the PE sample suppliers shall provide the Committee with verbal reports on PE sample results within five working days after receipt of PE sample results. In addition to a written evaluation report, the PE sample suppliers shall also send a cover memorandum in line-item summary format with the: names of PE samples within acceptable limits; names of target analytes correctly identified, but quantitated outside acceptable limits; and number of false

positives and/or negatives reported for each PE sample. The identities of false positives and/or negatives shall not be disclosed in the cover letter or memorandum.

(d) The majority of PE samples available from the USACE are in water and/or soil/sediment matrices. If only water PE samples are available for certain analytical parameters from the USACE, a commercial laboratory that passes the water PE samples will be considered for a multimedia validation of these parameters. However, if both water and soil/sediment PE samples are available for any parameters from USACE, a commercial laboratory must pass both matrices prior to consideration for a multimedia validation for these parameters. A commercial laboratory that passes water PE samples but fails the corresponding soil/sediment PE samples for any parameters will be considered for a validation of these parameters in water samples only. However, a laboratory that passes soil/sediment PE samples but fails the corresponding water PE samples will not be considered for validation of the failed parameters in any matrix type of samples, including soil/sediment samples.

(e) For volatile and semivolatile organic analyses, some compounds in the water or soil/sediment PE samples may not be the method-specific target compounds. A laboratory is required to use the NIST/EPA/MSDC or any other USEPA approved mass spectral library to tentatively identify and quantify up to ten non-target volatile organic compounds and twenty non-target semivolatile organic compounds that exhibit the strongest ion current signals. These compounds must not be system monitoring compounds. Identification of these compounds, based on spectral interpretation procedures, is evaluated and integrated into the evaluation process for volatile and semivolatile organic PE sample results. For metal analysis, the validation will be granted for one of the following four categories based on the number of metal elements in the PE samples passed:

- Category I: Eight RCRA metal elements (arsenic, barium, cadmium, chromium, lead, mercury, selenium, and silver.)

- Category II: Fourteen RCRA and Priority Pollutant (PP) metal elements (antimony, arsenic, barium, beryllium, cadmium, chromium, copper, lead, mercury, nickel, selenium, silver, thallium, and zinc.)

- Category III: Twenty-three USEPA CLP Target Analyte List (TAL) metal elements (aluminum, antimony, arsenic, barium, beryllium, cadmium, calcium, chromium, cobalt, copper, iron, lead, magnesium, manganese, mercury,

nickel, potassium, selenium, silver, sodium, thallium, vanadium, and zinc.)

- Category IV: Any other metal element(s) including the four metal elements (arsenic, cadmium, chromium, and lead) usually required for UST removal projects.

(f) Based on project requirements on metal analysis, one of the above four specific categories of metal PE samples will be selected for laboratory validation. A commercial laboratory may volunteer for any one of the four categories of metal PE samples as long as more metal elements than the project-required are analyzed. Normally, a commercial laboratory must satisfactorily pass all metal elements in a specific category prior to consideration for validation of the specific category of metal elements.

(9) If PE samples for a particular parameter such as dioxin, radioactivity, air toxics, etc. are not available from the USACE, the analysis of PE samples will be exempted until the appropriate PE samples for these particular parameters become available. The validation of a commercial laboratory for parameters without PE samples available will be based solely on the laboratory's qualification documents submitted to the Coordinator for review. The qualification documents shall include: copies of the laboratory’s LQMM; laboratory certificates or licenses; and the most recent two rounds of PE sample results from other government and/or private agencies. If the parameter is the only project-required chemical analysis, an on-site inspection may be waived.

(h) For the analysis of chemical warfare agents, their degradation products, and other scheduled compounds in the complex matrices, the primary contracts shall select chemical surety laboratories that have already been approved by the U.S. Army Edgewood Research, Development and Engineering Center (ERDEC) at Aberdeen Proving Ground, Maryland. The USACE will not send PE samples to or inspect the approved chemical surety laboratories. The USACE will contact the ERDEC for technical assistance and provide a list of approved chemical surety laboratories if requested.

(i) The acceptance of PE sample results also depends on whether the results are returned in a timely manner and no procedural problems are found during a follow-up laboratory inspection. The Coordinator will send a copy of the cover letter or memorandum from the PE sample suppliers evaluation reports to the laboratory for information and/or necessary action(s) by the laboratory. Due to confidentiality requirements, the true values

and/or two sigma confidence limits for any batch of volatile organic PE samples and soil/sediment PE samples shall not be released to commercial laboratories until the batch is discontinued. A commercial laboratory will be allowed to provide revised data for failed parameters if problems such as calculation or transcription errors can be identified. If a commercial laboratory is requested by the Coordinator to check its analytical data, the laboratory shall return revised data within five working days to the Coordinator.

(j) After data revisions, a commercial laboratory must pass, as a minimum, more than 50 percent of all PE samples, including project-specific and non-project-specific PE samples, within 40 working days from receipt of the first set of PE samples, or the validation process will be terminated. The Coordinator will notify all affected USACE TM/CORs immediately and suggest selection of another laboratory by the prime contractor for evaluation. After a commercial laboratory passes 50 percent of all PE samples within 40 working days, the Coordinator will contact the laboratory to schedule an on-site inspection within ten working days. Prior to an on-site inspection, the laboratory shall submit to the Coordinator a concise written statement describing the problems, solutions, and corrective actions taken or to be taken for the analytical parameters failed in its first attempt.

c. Step 3: On-Site Laboratory Inspection.

(1) Two Committee representatives will normally serve as the inspectors to inspect a commercial laboratory after Steps 1 and 2 have been satisfactorily completed. The inspectors shall contact and invite the USACE TM/COR(s) who initiated the evaluation request(s) and the USACE division laboratory(s) that serves as the QA laboratory(s) for the project(s) to send representatives to the inspection. The PE sample suppliers may also be requested to send technical experts if assistance is needed for the inspection. During an on-site laboratory inspection, the inspectors shall verify that:

- the organization and personnel are qualified to perform assigned tasks,

- adequate facilities and equipment are available,

- complete documentation, including chain-of–custody of samples, is being implemented,

- proper analytical methodology is being used without deviations,

- adequate analytical quality control (including reference samples, control charts, documented corrective actions, etc.) is being provided,

- acceptable data handling and documentation techniques are being used,

- adequate facilities and operations are installed to ensure laboratory health and safety, and

- proper waste disposal procedures are implemented.

(2) The on-site laboratory inspection helps to ensure that the laboratory is technically competent and that all the necessary quality control is being applied by the laboratory in order to deliver a quality product. The on-site inspection also serves as a mechanism for discussing weaknesses identified through PE sample analysis or other review of data deliverables. Lastly, the on-site inspection allows the inspector to monitor whether the laboratory has continuously and successfully implemented the recommended and/or required corrective actions that were made during previous on-site inspections by the USACE. Failure to have implemented past action items may be grounds for termination of the current validation process.

(3) Prior to the inspection, the inspectors shall review all appropriate project- and laboratory-specific documents including:

- scope of services, specifications, work plans, and/or chemical data acquisition plan, if available,

- LQMM and qualification documents,

- preliminary questionnaire,

- PE sample results and evaluation reports,

- previous inspection reports, if applicable, and

- previous performance on USACE HTRW projects based on the chemical quality assurance reports (CQARS) for projects that the laboratory has previously worked on.

(4) The on-site inspection generally takes eight hours and normally consists of three parts: entrance interview, laboratory tour, and exit interview. The entrance interview will be held with the upper laboratory management personnel (including laboratory director/managers, QA officer, and project personnel)

to discuss the upcoming USACE projects, the USACE QA program, the USACE review comments on the laboratory's LQMM, the PE sample results, and the laboratory's previous performance on USACE projects, if applicable. A copy of written comments on the LQMM shall be presented to the laboratory during the entrance interview. The inspectors will also present an overview of the laboratory's performance on PE sample analysis.

(5) A tour of the commercial laboratory will follow to examine the laboratory facilities, instrumentation, operation, maintenance, documentation, safety, waste compliance, etc. The audit tour is generally conducted in a manner that allows the following of a sample through the laboratory, and looking at all operations that a sample is exposed to during its transfer of custody, digestion/extraction, and analysis. This includes sample/digestate/extract storage, instrument calibration, SOPS, documentation, data review and reporting, etc. During the tour, the inspectors shall also examine the raw data of the PE samples and talk with the analysts who performed the analyses of any failed PE samples to determine the cause of failure and to decide if additional PE samples are needed for the failed parameters. The inspectors should adhere to the inspection guidelines and criteria in Appendix H and use the appropriate laboratory inspection checklists in Appendices I or J.

(6) At the conclusion of the laboratory tour, the inspectors shall request a 30-minute close door session to organize, review, and document the findings. After the close door session, an open exit interview will be held with laboratory personnel in which a summary of any deficiencies and recommendations is discussed. The format in Figure 2-2 can be used to document the meeting summary on deficiencies, recommendations, and/or any other findings, if applicable. The authorized representative of the laboratory shall be asked to sign the meeting summary to attest that the laboratory representative has reviewed the meeting summary with the inspectors. The laboratory has ten working days to submit written responses with supporting documentation to the deficiencies and/or recommendations to prevent possible validation termination. The responses shall address the corrective actions that have been taken or will be taken with proposed implementation and completion schedules. All deficiencies shall be corrected by the laboratory prior to performing USACE HTRW project work. Recommendations based on good laboratory practice for operations and management are for the laboratory's consideration.

2-4. Approval Procedures. Normally, within five working days after the inspection, the inspectors shall organize, document,

U.S. ARMY CORPS OF ENGINEERS
ON-SITE LABORATORY INSPECTION SUMMARY

LAB NAME/LOCATION: _____

DATE/TIME: _____

PURPOSE: This format documents any deficiencies and recommendations noted during the on-site laboratory inspection. The laboratory has ten working days to submit written responses with supporting documentation, including an implementation schedule for any corrective actions, to the deficiencies and recommendations to prevent possible validation termination.

MEETING ATTENDEES:

NAME	ORGANIZATION/TITLE	PHONE

Figure 2-2 On-Site Laboratory Inspection Summary

ON-SITE INSPECTION SUMMARY:

DEFICIENCIES :

Figure 2-2 On-Site Laboratory Inspection Summary (continued)

ON-SITE INSPECTION SUMMARY:

RECOMMENDATIONS:

OTHER FINDINGS:

ACKNOWLEDGMENT:

LABORATORY:_____

USACE INSPECTION TEAM:_____

Figure 2-2 On-Site Laboratory Inspection Summary (continued)

and verbally present the findings and the recommended validation status for the laboratory to the Committee for approval and/or concurrence. In the event that supportive documents from a laboratory are needed before a final decision by the Committee, the inspectors shall present a second presentation within five working days after receipt of the requested materials from the laboratory. A minimum of three members of the Committee must be present in the review meeting to determine the validation status of a commercial laboratory. The decisions of the Committee can be documented in the format shown in Figure 2-3. Normally, a parameter- and matrix-specific full validation for 18 months will be granted to a commercial laboratory after the laboratory has satisfactorily met all USACE HTRW laboratory validation criteria. The 18 months start from the date that the Committee first met after the inspection and agreed upon the laboratory's validation status. The guidelines for determination of validation status for a commercial laboratory are as follows:

a. For a commercial laboratory that passes all PE samples and has no deficiencies noted during the on-site inspection, a full validation status of 18 months will be granted for all analytical parameters that the laboratory has passed the associated PE samples.

b. For a commercial laboratory that passes all PE samples but has deficiencies noted during the on-site inspection, a full validation status of 18 months will be granted for all analytical parameters that the laboratory has passed the associated PE samples. However, validation will only be granted after the Committee reviews and accepts the written responses from the laboratory and the laboratory completes the implementation of corrective actions for the deficiencies.

c. For a commercial laboratory that does not pass all PE samples but has no other deficiencies noted during the on-site inspection, a full validation status of 18 months will be granted for all analytical parameters that the laboratory has passed the associated PE samples. Validation may also be granted for analytical parameters if it is determined during the on-site inspection that the failure was due to minor errors, such as errors in data calculation, transcription, etc. For any failed parameters caused by major errors (such as errors in analytical procedure, spectra interpretation, etc.) or unknown/unsure reasons, the laboratory must pass additional PE samples prior to consideration for validation of the additional parameters. In this case, one set of additional PE samples will be sent to the commercial laboratory that failed the first set of PE samples. Results of the additional set of PE sample analyses shall be returned to the PE sample suppliers and the Coordinator within

U.S. ARMY CORPS OF ENGINEERS
LABORATORY EVALUATION COMMITTEE
VALIDATION REVIEW MEETING SUMMARY

LAB NAME/LOCATION:_____

REVIEW MEETING DATE/TIME:_____

PURPOSE: This format documents the final committee decisions on the validation status of a contract laboratory inspected by the staffs of the Army Corps of Engineers.

MEETING ATTENDEES:

NAME	ORGANIZATION/TITLE
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	
11.	
12.	

INSPECTOR'S RECOMMENDATIONS TO COMMITTEE:

Figure 2-3 Validation Review Meeting Summary

VALIDATION REVIEW MEETING SUMMARY:

MAJOR FACTORS SUPPORTING COMMITTEE DECISIONS:

FINAL COMMITTEE DECISIONS:

SIGNATURES OF COMMITTEE MEMBERS:

1.		2.	
3.		4.	
5.		6.	
7.		8.	
9.		10.	
11.		12.	

Figure 2-3 Validation Review Meeting Summary (continued)

five or ten working days, depending on the number of additional PE samples required. The Committee will make the final decision on the pass/fail status of PE sample analysis or any additional work needed to pass PE samples. If a commercial laboratory fails to pass the additional set of PE samples, no validation status will be granted for the additional parameters.

d. For a commercial laboratory that does not pass all PE samples and also has other deficiencies noted during the on-site inspection, similar procedures and criteria as described in paragraph 2-4.c. will be used to determine the laboratory's validation status. However, validation will only be granted after the Committee reviews and accepts the written responses from the laboratory and the laboratory completes the implementation of corrective actions for the deficiencies.

e. For a commercial laboratory that has deficiencies noted during the on-site inspection, but failed to submit acceptable responses or to satisfactorily complete corrective actions within the required time frame, no validation status will be granted. A commercial laboratory that is considered to have failed on attempted validation shall wait for six months prior to repeating the validation process, and then the process is only initiated by a written request from a USACE TM/COR. If a commercial laboratory fails the laboratory validation process during any of the three major steps mentioned previously, another commercial laboratory or a prevalidated commercial laboratory must be selected by the prime contractor for evaluation. If another non-validated laboratory is selected, the prime contractor will be responsible for the expense of this additional laboratory validation.

f. A commercial laboratory, that is exempted from PE sample analysis due to lack of suitable PE samples from USACE, will be granted a six month conditional validation. The performance of a commercial laboratory granted a conditional validation status will be closely monitored by the USACE TM/CORs, the USACE division laboratories that serve as the government QA laboratories, and the Committee during the conditional period. Prior to the end of the conditional validation, the Committee will review the case and determine the appropriate actions required for a full validation for an additional 12 months. Normally, if no performance problems are noted during the probation period, a full validation will be granted. The Coordinator shall keep all affected USACE TM/CORs informed of any changes of validation status of commercial laboratories.

g. For a commercial laboratory inspected by a "non-committee representative" inspector for UST removal

projects, the same guidelines addressed above apply. The inspector(s) shall send a written inspection report and all appropriate documents to the Committee for technical review and approval. The Committee will make the final decision on a laboratory validation status based on all information available including the inspectors' written inspection reports.

h. For a mobile laboratory, the above mentioned guidelines in paragraphs 2-4.a. through 2-4.f. apply. However, the validation status of a mobile laboratory will be terminated when the laboratory is demobilized.

2-5. Inspection/Evaluation Report.

a. If no deficiencies were noted, a laboratory inspection and evaluation report shall be prepared by the inspectors and submitted to the HTRW MCX management for approval within ten working days after the inspection date. If deficiencies were noted and the laboratory provided satisfactory responses, the report shall be submitted within five working days after receipt of the satisfactory responses.

b. The inspection and evaluation report shall contain, but not be limited to, the information listed in Table 2-1. Upon approval by the HTRW MCX management, a cover letter and the inspection report including review comments on LQMM, PE sample evaluation reports, and laboratory's written responses to deficiencies shall be immediately sent to the USACE TM/CORs and the commercial laboratory. The cover letter shall specify the methods, matrices, time period, and limitations for which the validation is granted, and the corrective actions that have to be taken by the laboratory if applicable. A commercial laboratory must rectify all deficiencies prior to the initiation of field studies and sample analyses. During the 18-month period, the Committee reserves the right to send additional PE samples or to conduct additional inspections as necessary. The laboratory validation does not guarantee the award of any contracts from a USACE TM/COR or a prime contractor. For UST removal projects, although the inspections may not be conducted by the Committee representatives, all reports generated by the inspectors shall follow the format given in this manual. All cover letters shall originate from the HTRW MCX.

Table 2-1. Sample Format for Inspection Report

1. General

   a. Date of Inspection.
   b. Name, office symbol, and phone number of inspector.
   c. Contract(s) for which the laboratory will be used.
   d. Description of contract.
   e. General information of the laboratory (Business name, street address, phone, how long in business, number employed, type of services offered, and other pertinent information.)

2. Summary of Inspection Results

   a. Overall comments on the laboratory's technical capabilities in meeting the project requirements.
   b. The validation status and expiration date of the laboratory.
   c. Major deficiencies or concerns to be corrected or be aware of for USACE HTRW projects.

3. Interviews

   a. Entrance

      - Introduction to the USACE QA program.
      - Overview of USACE HTRW laboratory validation procedures.
      - Discussion of the upcoming USACE project(s).
      - Presentation and discussion of the USACE comments on the laboratory's LQMM.
      - Overview and discussion of PE sample results.
      - Discussion of the laboratory's past performance on USACE HTRW projects, if applicable.

   b. Exit

      - Discussion of deficiencies to be corrected.
      - Recommendations based on good laboratory practice.
      - Action items for the laboratory's response.

Table 2-1. Sample Format for Inspection Report (continued)

4. General On-Site QA Evaluation

   a. Adequacy of organizational structure to maintain its stated capabilities in operation and management.
   b. Adequacy and maintenance of facilities and equipment.
   c. Quality, age, availability, scheduled maintenance, and performance of instrumentation.
   d. Staff qualifications, experience, and training programs.
   e. Availability, appropriateness, and utilization of SOPs .
   f. Reagents, standards, and sample storage facility.
   g. Bench sheets and analytical logbooks maintenance and review.
   h. Data package and data management.
   i. Availability and use of control charts.
   j. Waste disposal compliance.

5. Conclusions

   a. Deficiencies that must be corrected by the laboratory prior to approval for validation.
   b. Recommendations for laboratory's consideration.
   c. Other findings of interesting or important nature.
   d. Concerns from the laboratory on USACE HTRW projects.
   e. Laboratory's responses to deficiencies and recommendations, if available.
   f. Action items for the laboratory’s response.